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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,923	07/14/2003	Clayton M. Hardman	P/55-3	7964

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EXAMINER	
SNAY, JEFFREY R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,923	HARDMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey R. Snay	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebersole (4,219,335) in view of Baselt (5,981,297), Colin (5,925,573) and either Jeffers (4,413,296) or Mallary (5,654,854).

Ebersole teaches immunochemical testing using tagged reagents. An analyte such as an antigen or antibody was determined in body fluid by depositing a sample of the blody fluid on a surface (2) coated with a receptor reagent specifically reactive with the analyte resulting in a complex. An immune reagent capable of affecting electrical reactance which was specifically reactive with the receptor reagent or complex was then added and the electrical reactance measured. For example, serum containing IgG was reacted with anti-human IgG on a Nylon 6 film, the resultant test zones were treated with great anti-human IgG tagged with magnetic particles, and the magnetized reaction surface analyzed by a magnetic particle detector. This system may be used manually, but it is readily adaptable to automated operation. For magnetic particles, magnetic pick-up heads such as those found in standard tape recording equipment may be used. It is possible to arrange the receptor reagent on the surface in bands or to induce a periodic magnetization on the surface as that produced by a magnetic tape recording system and then to move the surface at a particular rate past a detector which will monitor frequency. The test surface can be flat or it can have depressions or dimples in which each test is conducted. The presence of a change in electrical reactance such as magnetic activity can be determined, even when a very small amount of the reactance tags is present. Therefore, each test will usually require only a droplet of body fluid and the test area can be very small. Consequently, a large number of discrete test areas and if desired, reference areas, can be arrayed on a single card or tape. The discrete areas may be either a series of tests for different selected proteins or a series of tests for the same protein. Since the method of this invention utilizes electronic rather than

visual inspection, it is readily adaptable to automated operation. A preferred system for the practice of this invention would include a station for entering the necessary test cards for the desired test. Cards may be entered individually or in a group as required. The cards are moved automatically to a sample addition station where a droplet of a patient's body fluid is applied to each of the test areas on the card. An automated device may include temperature control and a station for equilibration of the body fluid on the test areas for predetermined times. The card is then moved to a station where the immune reagent is applied to each of the test areas. Again, there may be temperature control and equilibration systems incorporated. Next, excess immune reagent is removed, and the card is then examined for the presence of reactance tags remaining in the test by measuring changes in electrical reactance of the card test areas with a detector capable of determining the presence of magnetic particles. It is also possible to perform each operation on a card maintained at a single location in an automated or semi-automated device. Ebersole does not teach the detector detecting the particles with a giant mangetoresistive effect or specific means to position the detector in proximity to each surface.

Baselt teaches a system for performing assays in a manner substantially similar to Ebersole. In Baselt, the detector for the proximity of paramagnetic particles is based on the giant magnetoresistive effect (see Figures 2-7, column 3, lines 18-66, and columns 7-8). Detection of a single particle is taught as possible.

Colin teaches an assay device similar to Ebersole in which the magnetic particles are detected by a detector (4) having an electromagnetic sensor 6) formed, in a

traditional fashion, as a read head for an audio or video tape (column 6, lines 3-19). Figure 3 teaches a single detector that is movable to a number of different detection locations.

Jeffers teaches a thin film mangetoresistive head for use in reading magnetic data recorded on a storage device such as a film (audio or video tape).

Mallary teaches a magnetoresistive sensor for use in reading magnetic data recorded on a storage device such as a film (audio or video tape). Column 1, lines 28-32 teach that a giant magnetoresistive element is known as one type of this sensor. Lines 38-43 teach that magnetoresistive sensors are known to have a sensitivity that exceeds other known magnetic sensors such as inductive sensors.

It would have been obvious to one of ordinary skill in the art to incorporate a mangetoresistive sensing head as taught by Baselt, Jeffers or Mallary and in particular the giant magnetoresistive sensor of Baselt or Mallary because of their recognized advantage of greater sensitivity as taught by Baselt and Mallary. It would have been obvious to one of ordinary skill in the art to provide the automated Ebersole device with a detection head as taught by Colin or to provide multiple detection areas in the detector as taught by Baselt because of the ability to measure multiple detection sites, as taught by Baselt and Colin.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,592,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by, or differ only nominally from, the patented claim.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs